



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,528	11/27/2006	Naohiko Hirota	278432US0PCT	3047
22850	7590	12/18/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
RAGHU, GANAPATHIRAM				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
12/18/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdoCKET@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

Office Action Summary

Application No.

10/550,528

Applicant(s)

HIROTA ET AL.

Examiner

GANAPATHIRAMA RAGHU

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 10/02/08; 01/30/08; 12/11/07; 05/09/06; 12/22/05

Detailed Action

Claims 1-13 are pending in the instant application and are under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/JP04/04217 filed on 03/25/2004 and claims the priority date of Japanese application 2003-083924 filed on 03/25/2003. Examiner notes that the certified copies of the application 2003-083924 filed on 03/25/2003 is provided. However, English translation for the said Japanese application is not provided.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 10/02/08, 01/30/08, 12/11/07, 05/09/06 and 12/22/05 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered and initialed the IDS statements.

Specification-Objection/Sequence Compliance

Applicants are advised that the application is not in compliance with 37 CFR §§ 1.821-1.825. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825. Specifically, applicants are required to comply with the sequence rules by inserting the sequence identification numbers of all sequences within the claims and /or specification. It is particularly noted that Fig. 5 are sequences, but applicant fails to provide the SEQ ID NO: (sequence identifier) to these sequences either in the figures or in the figure description. Sequences must be referred to by their sequence identifiers, see particularly 37 CFR 1.821(d). If the sequences appearing in

the specification do not have SEQ ID NO: assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification. Failure to correct the deficiency will be held a non-responsive to this Office action.

Claim Objections

Claim 13 is objected to, due to the following informality: Claim 13 recites the abbreviation/term "LOX-1" in the claim. Examiner suggests at least in the first recitation of the abbreviation, expanding the term to recite the full form of what the abbreviation stands for. Appropriate correction is required. For examination purposes, examiner interprets abbreviation/term "LOX-1" stands for Lipoxygenase-1.

Double Patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-25 and 27-35 of co-pending application 12/505,723 (Hirota et al.,). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an

examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir.1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although, the conflicting claims are not identical, they are not patentably distinct from each other. Claims 7-9 of the instant application cannot be considered patentably distinct over claims 14-25 and 27-35 of co-pending application 12/505,723 (Hirota et al.), when there is specifically disclosed embodiment that supports claims 14-25 and 27-35 of co-pending application 12/505,723 (Hirota et al.) and falls within the scope of the claims 7-9 herein. In the instant case the specification of co-pending application 12/505,723 (Hirota et al.) discloses as a preferred embodiment; a product produced from a barley plant wherein the barley plant has mutation in the LOX-1 gene causing a total loss of LOX-1 activity. Therefore, the invention of claims 7-9 of the instant invention are deemed an obvious variation of the invention of claims 14-25 and 27-35 of co-pending application 12/505,723 (Hirota et al.,).

Claim Rejections 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2 and 10-12 are rejected under 35 U.S.C. 101 because the claims could read on a non-statutory subject matter. The claims are drawn to "A barely lipoxigenas-1 mutant gene ...A nucleic acid...", which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests

amending the claim to recite "An isolated barely lipoxygenas-1 mutant gene ...An isolated nucleic acid...", to show the hand of man and in order to overcome the rejection.

Claim Rejections: 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9, line 2 recites "... using ...", since the claim does not set forth any steps involved in the method, it is unclear what method/use applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 9 is not clear and confusing. Claim 9 does not contain an active step, as said claim is directed to "production of an alcoholic beverages process...", it is unclear what steps in the method of "alcoholic beverages process ...", applicant is intending to encompass as said claim does not disclose "an event" that results or contributes to "alcoholic beverages process ...", as using the material of claim 7 or 8 in any manner will not result in the production of alcoholic beverages. A claim is indefinite where a key step is missing from a method and how this method is actually practiced. Examiner suggests amending claim 9 to disclose "an event" that results or contributes to "production of an alcoholic beverages process...". A claim is indefinite where it merely recites a method without any active,

positive steps delimiting how this method is actually practiced. Clarification and correction is required.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections: 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claim 1 and claims 2-9 depending therefrom is rejected under 35 U.S.C. 112, first paragraph. The specification is enabling for an isolated barley lipoxygenase-1 (LOX-1) mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having diminished LOX-1 activity (paragraph [0018] of specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific

mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene. However, the specification does not reasonably provide enablement for any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-9 are so broad as to encompass any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and encoded polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated barley lipoxygenase-1 (LOX-1) mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having diminished LOX-1 activity (paragraph [0018] of

specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable (for example, see Whisstock et al., 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims 1-9 which encompasses any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said genomic sequence and detection of

undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure. The specification does not enable the full scope of claims, because the specification does not establish: (A) the structure of all LOX-1 gene including variants, mutants and recombinants wherein the splicing donor site of the 5th intron is mutated; (B) the general tolerance of the polypeptide and the polynucleotide encoding LOX-1 to said modification and extent of such tolerance; (C) a rational and predictable scheme for said modification with any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function either diminished or enhanced LOX-1 activity; (D) defined core regions/motifs involved in the desired catalytic activity of encoded polypeptide; (E) the tertiary structure of the molecule and folding patterns that are essential for the desired activity and tolerance to modifications; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides and encoded polypeptides of undefined structure with an enormous number of modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166

USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the following reasons.

Claim 1-9 (as interpreted) are directed to any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said

genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

There is no structure-function correlation with regard to the members of the genus of polynucleotides and encoded polypeptides as claimed in claims 1-9. The specification discloses the structure of an isolated barley lipoxygenase-1 (LOX-1) mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having diminished LOX-1 activity (paragraph [0018] of specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method

comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene of the claimed genus. The specification lacks description of any additional species i.e., any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with undefined LOX-1 activity (enhanced or diminished), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure by any relevant, identifying characteristics or properties or structure correlated with function and therefore one of skill in the art would not recognize from the disclosure that applicants' were in possession of the claimed invention. The art also teaches, even highly structurally homologous polynucleotides and encoded polypeptides do not necessarily share the same function and conversely functionally similar molecules do not necessarily have similar structures. For example proteins having similar structure have different activities; Witkowski et al., (Biochemistry 38:11643-11650, 1999) teaches that one conservative amino acid substitution transforms a β -ketoacyl synthase into a

malonyl decarboxylase and completely eliminates β -ketoacyl synthase activity. Similarly, Wishart et al., (J. Biol. Chem., 1995, Vol. 270(10): 26782-26785) teach that a single mutation converts a novel phosphotyrosine binding domain into a dual-specificity phosphatase.

Hence, the recited genera of polynucleotides and encoded polypeptides are interpreted to have widely variable structures, since minor changes may result in changes affecting function and no additional information correlating structure with function has been provided.

Furthermore, "Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features" (See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895).

Therefore, given the lack of description of representative species encompassed by the genus of polynucleotides and encoded polypeptides and modifications, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Allowable Subject Matter/Conclusion

None of the claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims,

Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652